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10/563,637	06/12/2006	Christopher Milton Mathew Franco	19460	4137

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EXAMINER	
GUPTA, ANISH	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,637	FRANCO ET AL.	
	Examiner	Art Unit	
	ANISH GUPTA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *1-35,37 and 40-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36,38 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6-19-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group IX, claims 36, 38, 39 in the reply filed on 9-8-08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicants also elected SEQ ID NO 7 as the species for examination. The elected species was free of the prior art. However, since the claim also stated variant the claims have been examined with this limitation. Since prior art was found for variants, the claim is rejected.

Claims 36, 38 and 39 are examined in this Application. Claims 1-35, 37 and 40-41 are withdrawn form consideration.

Claim Objections

2. Claim 36 is objected to because of the following informalities:

The claim recites "A novel, isolated." Applicant should amend the claims to delete novel since novelty is not describe the claimed product in terms of function or structure.

It is noted that claim 36 claims a specific nucleic acid sequence. Applicants should place sequence identifiers as required by 37 CFR 1.821 (d).

Appropriate correction is required.

Specification

3. The abstract of the disclosure is objected to because the specification contains nucleic acid sequences. However, the specification does not contain sequence identifiers as required by 37 CFR 1.821 (d). Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 36, 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites <400>7 or <400>1. It is unclear from the claim what is defined to be <400>.

In claim 36 for (f) it is unclear what aci corresponds to.

In claim 36, the claim states that the anctinomycete characterized either by a nucleic sequence corresponding to the nucleotide sequence substantially as set forth in <400>7. Assuming that <400>7 refers to a specific sequence, it is unclear what substantial correspondence to this sequence would qualify as. That is to say it is unclear what percent of homology is necessary to render a sequence "substantially" corresponding to the sequence.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 36, 38, 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of

California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

For written description, the analysis (a) considers actual reduction to practice, (b) disclosure of drawing or structural chemical formulas, (c) sufficient relevant identifying characteristics in the way of complete/partial structure or physical and/or chemical properties, functional characteristics when coupled with known or disclosed.

In the instant case, the claims are drawn An actinomycete charaterised either by a nucleic acid sequence corresponding to the nucleotide sequence substantially as set forth in SEQ ID 7 or variants, mutants or homolgoues of actinomycete. Claims 38 and 39 recite metabolites derived from the nucleic acid sequence and antibodies directed to the actiomycete or the metabolites. This recitation does not provide written description for the claimed invention. The specification states that the variation or mutation characterising such an actinomycete may take any form including a genetic or a non-genetic variation or mutation. The subject variation or mutation may be naturally or non-naturally occurring.

(a) actual reduction to practice/(b) disclosure of drawing or structural chemical formulas:

The specification states that the variation or mutation characterising such an actinomycete may take any form including a genetic or a non-genetic variation or mutation. The subject variation or mutation may be naturally or non-naturally occurring. The specification however fails to disclose any variant, mutant or homologue that is correspond to SEQ ID NO 7. The specification only describes the variant or mutant in a generalized manner without providing any species.

This is also true for metabolites and antibodies. The specification fails to provide any species that correspond to a metabolite or antibody. The specification states that a "metabolite" should be understood as a reference to any proteinaceous or non-proteinaceous molecule produced by the subject endophytic actinomycetes or produced by the plant in response to the actinomycete colonisation or actinomycete metabolite actions which directly or indirectly modulate the metabolism or other functional activity of the host plant. The specification fails to provide a single example of a proteinaceous or non-proteinaceous molecule that would be a metabolite for SEQ ID NO 7 or an antibody against SEQ ID NO 7.

(c) sufficient relevant identifying characteristics in the way of complete/partial structure or physical and/or chemical properties, functional characteristics when coupled with known or disclosed:

As stated above, the specification defines variant as mutation characterising such an actinomycete may take any form including a genetic or a non-genetic variation or mutation. The subject variation or mutation may be naturally or non-naturally occurring. While the specification provides the sequence for SEQ ID NO 7, the specification does not describe the portions of the sequence in SEQ ID NO 7 that cannot be modified and are necessary to impart activity to encode a protein. One could not readily conclude, based on structure alone, that a "75%" homologous

sequence would have the requisite activity.

Similarly, the metabolites and antibodies are also defined solely by functional limitations. The specification defines "metabolite" is a reference to any proteinaceous or non-proteinaceous molecule produced by the subject endophytic actinomycetes or produced by the plant in response to the actinomycete colonisation or actinomycete metabolite actions which directly or indirectly modulate the metabolism or other functional activity of the host plant. However, the specification fails to provide any specific structures for the protein or non-protein molecules that could be construed as metabolites. Similarly, for antibodies, the specification fails for provide any relevant identifying characteristics in the way of complete/partial structure.

(d) Representative number of examples

Beyond SEQ ID NO 7, the specification fails to provide any examples that could be construed as variant, homologs, or mutants. Given the broad definition provided for variant, mutant, and homologs, the claims can encompass thousands of different sequences form SEQ ID NO 7. However, the specification fails to provide a single example that would fall within the broad definition of the claimed invention. This is also true for metabolites and antibodies. The definition for metabolites is all encompassing since they can include any compound that remotely has activity directly or indirectly to modulate the metabolism or other functional activity of the host plant. The specification does not provide a single compound, either a protein, peptide or small molecule, that would be considered a metabolite for SEQ ID NO 7. The specification simply fails to provide a representative number of species for the broad genus claimed for variants of SEQ ID NO 7, metabolites and antibodies. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope

the claimed invention achieves and the problems the invention will hopefully ameliorate.").

Finally, Recently in Ex Parte Kubin ,83 USPQ2d 1410 (Bd. Pat. App. & Int. 2007), Board of Patent Appeals and Interferences, found lack of written description in a claim drawn to a genus of polynucleotides encoding polypeptides "at least 80% identical to amino acids 22-221 of SEQ ID NO:2" The Board stated:

> "Claim 73 is to a genus of polynucleotides encoding polypeptides "at least 80% identical to amino acids 22-221 of SEQ ID NO:2" which bind to CD48. Sufficient description to show possession of such a genus "may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features. *See University of Rochester*, 358 F.3d at 927, 69 USPQ2d at 1895.
>
> In this case, Appellants have sequenced two nucleic acids falling within the scope of claim 73 and three fusion proteins whose nucleotide sequences would fall within the scope of claim 73. None of these sequences varies amino acids 22-221 of NAIL, and thus these sequences are not representative of the genus.
>
> Appellants also have described how to make and test other sequences within claim 73 sufficiently to satisfy the enablement requirement. **However, they have not described what domains of those sequences are correlated with the required binding to CD48, and thus have not described which of NAIL's amino acids can be varied and still maintain binding. Thus, under *Lilly* and its progeny, their Specification would not have shown possession of a sufficient number of sequences falling within their potentially large genus to establish possession of their claimed genus.** *Cf. Enzo*, 323 F.3d at 964, 63 USPQ2d at 1612 ("if the functional characteristic of … binding to [CD48] were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed," the written description requirement may be met).
>
> Without a correlation between structure and function, the claim does little more than define the claimed invention by function. That is not sufficient to satisfy the written description requirement. *See Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 ("definition by function … does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is")." See Kubin at 1417.

Here, similar to Kubin, the specification fails to described what domains of those sequences

are correlated with the required activity, and thus have not described which of the SEQ ID 7 amino acids can be varied and still have activity. Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Finally, the specification lacks complete deposit information for the deposit of EN2, EN3 etc…. It is not clear that EN's identified by the AGAL deposit numbers are known, publicly available or can be reproducibly isolated from nature without undue experimentation.

Exact replication of an nucleic acid is an unpredictable event. Although applicant has provided a written description of a method for generating and isolating the specified nucleic acids, this method will not necessarily reproduce nucleic acids and which are chemically and structurally identical to those claimed. It is unclear that one of skill in the art could derive nucleic acids identical-to those claimed. Undue experimentation would be required to screen all of the possible nucleic acid species to obtain the claimed species.

Because one of ordinary skill in the art can not be assured of the ability to practice the invention as claimed in the absence of the availability of the antibodies listed in claims 36, a suitable deposit of the molecules designated EN2, EN3 etc.. for patent purposes, evidence of public availability of the claimed cell lines or evidence of the reproducibility without undue experimentation of the claimed cell lines, is required.

Applicants have not made a referral to the deposit of the antibodies in the specification. There is insufficient assurance that all required deposits have been made and all the conditions of 37 CFR 1.801-1.809 met.

If the deposits are made under the provisions of the Budapest Treaty, filing of an affidavit or

declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Shimizu et al. (J. Gen. Plant Pathol. 66).

The claim are drawn to a variant of a nucleic acid of SEQ ID NO 7.

The reference disclose enddophytic actinomycetes as a controlling agent against fungus disease (see abstract). Note that the reference disclose that the enddophytic actinomycetes obtained exhibited broad antibmicrobial activity against bacteria and yeast (see page 363). The instant specification defines "variant" of the subject actinomycete should be understood to mean a microorganism which exhibits at least some of the functional activity of the actinomycete of which it is a variant or mutant (see page 3 of the specification). The specification also states that the

enddophytic actinomycetes exhibit antifungal activity. Since the prior art teaches enddophytic actinomycetes as a controlling agent against fungus, this is deemed to be a variant of the claimed invention.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/
Primary Examiner, Art Unit 1654